UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/485,163	06/07/95	[illegible]	5	[illegible]

18N2/0815

JOHN P WHITE
COOPER & DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036

EXAMINER	
BROWN, K	

ART UNIT	PAPER NUMBER
1812	

DATE MAILED: 08/15/97

8/15/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
[illegible]	[illegible]	[illegible]	[illegible]

EXAMINER

19N2/0807

JOHN P WHITE
COOPER & DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036

ART UNIT | PAPER NUMBER

1812

DATE MAILED: 08/07/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 5/19/97

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 30-35, 44-46 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 30-35, 44-46 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 19
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

1. Claim 43 has been canceled and claims 44-46 have been added. Therefore, claims 30-35 and 44-46 are examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. Claims 30-35 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Capon et al. (U.S. Pat. No. 5,565,335).

Claims 30-35 are rejected for reasons of record set forth in Paper No. 16, pages 3-5. Newly added claims are also rejected over '335 because '335 also teach an expression vector comprising DNA encoding CD4-IgG (col. 11, lines 16-30 and col. 12, line 49 to col. 13, line 10), a method of producing CD4-IgG (col. 14, lines 29-42), and a method of producing CD4-IgG in CHO cells (col. 12, lines 65-66). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to follow the teachings and motivations of '335 to make any CD4-IgG homodimer, including the claimed CD4-IgG2 homodimer, using an expression vector comprising DNA encoding CD4-IgG2, and to use host cells comprising this expression vector to produce CD4-IgG2 in CHO cells, as suggested by '335.

4. Applicant's arguments filed 19 May 1997 have been fully considered but they are not persuasive.

Applicant argues that there is no close structural similarity between the CD4-IgG1 exemplified by '335 and the CD4-IgG2 taught by Applicant, nor that any of the molecules taught

by Capon exhibits sufficient close structural similarity to that instantly claimed. Applicant also asserts that Capon does not teach or suggest Applicant's polypeptide. However, Capon specifically teaches a CD4-IgG2 fusion protein (col. 7, lines 47-49). Capon also exemplifies a CD4-IgG1 fusion protein which is structurally almost identical to CD4-IgG2. Both the instantly claimed CD4-IgG2 and the CD4-IgG1 taught by Capon appear to have identical CD4 extracellular domains comprising the N-terminal domain of the homodimer, and differ only in that the C-terminal domain of the homodimer is IgG1, in the case of Capon, or IgG2, in the instant case. It was well-known in the art at the time the invention was made that the constant domains of IgG1 and IgG2 are both structurally and functionally related to one another, and have a sequence identity of about 95% (see 5,431,793, col. 7, lines 42-44).

Applicant asserts that the disclosure of Capon of a method for producing the CD4-IgG2 is not a proper basis for determining whether the claimed compound is obvious. This argument is unpersuasive because Capon's method was not the basis of obviousness. Instead, Capon's express teaching that suitable fusion proteins are obtained from IgG2 is the basis. This teaching was pointed to in the rejection of record, Paper No. 16, page 4, lines 3-5. It is the composition itself that is suggested by Capon. Capon discloses a motivation for producing the claimed fusion protein (col. 1, lines 11-15 and col. 10, line 66 to col. 11, line 4; also see discussion in Paper No. 16, page 4) and also provides a method for producing the CD4-IgG2 DNA, vectors, host cells, method of producing the protein recombinantly and the protein itself. Thus, Capon provides not only a teaching for the composition CD4-IgG2, but also a method for producing the claimed

compound and a reasonable expectation of success since Capon exemplifies CD4-IgG1, a highly structurally and functionally similar compound.

Applicant urges that there is no reasonable expectation of success in obtaining a functional CD4-IgG2 because of the amino acid differences between CD4-IgG1 and CD4-IgG2. However, as discussed above, since IgG1 and IgG2 are virtually identical in their constant domains, one having ordinary skill in the art would have the reasonable expectation that one could substitute the constant domain of IgG2 for that of IgG1 in the molecule taught by Capon and retain the functional properties of the fusion protein, especially since Capon specifically teaches that the constant domain of any IgG isotype could be used. In addition, there is no requirement under 35 USC 103 that there be absolute predictability of success, but rather only a reasonable expectation of success in producing an obvious variant of a known compound.

Applicant lastly argues that there is no motivation to make the specific amino acid alterations between CD4-IgG1 and CD4-IgG2. This argument is unpersuasive because the only differences in amino acid sequence between CD4-IgG1 and CD4-IgG2 are those amino acid residues which differ between the constant domains of IgG1 and that of IgG2. Since Capon suggests a CD4-IgG2 fusion protein, those minor amino acid sequence differences between CD4-IgG1 and CD4-IgG2 were known by Capon or by any one having ordinary skill in the art. Thus, one having ordinary skill in the art following the teachings of Capon would have produced a CD4-IgG2 with the same specific amino acid alterations as that instantly claimed.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Brown whose telephone number is (703) 308-3668. The examiner can normally be reached on Mondays through Thursdays and alternate Fridays from 8:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached on (703) 308-2957.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**stephen.walsh@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

KEB
4 August 1997

Stephen Walsh
STEPHEN WALSH
SUPERVISORY PATENT EXAMINER
GROUP 1800